REMARKS

Claims 2, 6, 10, 15, 29-33 and 41-42 are pending. Claims 5, 7-8, 14, 16-17, 34-36 and 38-40 are withdrawn from further consideration by the Examiner because they are drawn to non-elected species of elected Group II. Claims 3-4 and 11-13 have been cancelled, as the subject matter of these claims has been incorporated into independent claims 2 and 10. Support for new Claims 41 and 42 is found in pending claims 31, 32, and 33 and in original claim 4.

Applicant reiterates that the species elections in this application were made with the understanding that should allowable subject matter be found, the Applicant is entitled to consideration of a generic claim (i.e., claims 2, 10, 31 and 32) encompassing additional species of PBMC (e.g., withdrawn claims 7 and 8 and T cell activators (e.g., withdrawn claims 5 and 34-36).

Applicant notes that an Abstract was submitted with the application as filed (see attached postcard). However, as the Examiner indicates that the Abstract is missing, a copy of the Abstract as filed is enclosed on a separate sheet.

Formal Drawings, in compliance with 37 CFR are submitted. In addition, the Brief Description of the drawings for Figures 7, 8, 15 and 17 has been amended to correspond to the Formal Figures.

The title of Example 1 has been amended so that it is now legible.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 2-4, 6, 10-13, 15, 29-33 and 37 are rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. Independent Claims 2, 10, 31 and 32 have been amended to disclose components comprising the suppressive composition. Applicant respectfully submits that PBMC and T cell activators are sufficiently described in the specification to enable a person of skill in

the art to make and use the invention. For example, PBMC are defined in the specification at page 13, lines 10-16. Methods for enriching particular subsets from the PBMC are described at page 15, lines 9-25. T cell activators are defined in the specification at page 17, line 7 through page 18, line 18. Thus, there is adequate disclosure in the specification to support generic claims disclosing PBMC and T cell activators. Accordingly, Applicant respectfully requests withdrawal of the rejection.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 2-4, 6, 10-13, 15, 29-33 and 37 are rejected under 35 U.S.C. § 112, first paragraph for lack of written description. Independent Claims 2, 10, 31 and 32 have been amended to disclose components comprising the suppressive composition. Moreover, PBMC are described in the specification at page 13, lines 10-16. Methods for enriching particular subsets from the PBMC are described at page 15, lines 9-25. Finally, T cell activators are described in the specification at page 17, line 7 through page 18, line 18. Thus, there is adequate written disclosure in the specification to support generic claims disclosing PBMC and T cell activators. Accordingly, Applicant respectfully requests withdrawal of the rejection.

Double Patenting Rejections

Claims 2-3, 6, 10-12 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-4 of U.S. Patent No. 6, 447, 765. The double patenting rejection appears to be based on the fact that the present invention and the issued patent are directed to the same general invention.

Claims 3 and 11-12 have been cancelled. Thus, the rejection is moot as applied to these claims.

Independent claims 2 and 10 disclose a method for treating donor cells to ameliorate graft versus host disease comprising treating donor PBMC with a suppressive composition comprising TGF-β, IL-2 and a T cell activator.

Claim 1 of U.S. Patent No. 6, 447, 765 discloses a method for treating donor cells to ameliorate graft versus host disease comprising treating donor PBMC with a suppressive composition comprising TGF-β. Claim 4 discloses that the suppressive composition may comprise IL-2. However, claims 1, and 3-4 do not teach a suppressive composition comprising a T cell activator. Moreover, none of the other references of record cure this defect.

In determining whether a non statutory basis exists for a double patenting rejection, the first question to be asked is whether any claim in the application defines an invention that is merely an obvious variation of an invention claimed in the patent. See M.P.E.P. § 804 II.B. In other words, a double patenting rejection relies on a comparison of the claims in the pending application with the claims in the issued application. See M.P.E.P. § 804 III.

Applicants submit that Claims 1 and 3-4 U.S. Patent No6, 447, 765 do not disclose a suppressive composition comprising T cell activators. Thus, the claims in the present application are not an obvious variation of the claims in U.S. Patent No. 6, 447, 765. Accordingly, Applicant request that the double patenting rejection be withdrawn.

Claims 4, 13, 33, and 37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-4 of U.S. Patent No. 6, 447, 765 in view of U.S. Patent No. 6, 406, 696.

Claims 4, 13 and 37 have been cancelled and thus the rejection is moot as applied to claims 4 and 13.

Claim 33 depends from Independent Claims 2, 10, 31 and 32 and thus discloses a method for ameliorating graft versus host disease comprising treating donor PBMC with a suppressive composition comprising TGF-β, IL-2 and the T cell activator anti-CD3.

The claims of U.S. Patent No. 6, 447, 765 are discussed above.

The claims of U.S. Patent No. 6, 406, 696 disclose a method for stimulating an immune response comprising activating T cells with anti-CD3. However, the claims of U.S. Patent No. 6, 406, 696 do not teach or disclose a method for using a suppressive composition comprising TGF-β, IL-2, and a T cell activator to ameliorate graft versus host disease.

An obviousness-type double patenting rejection is analogous to the obviousness rejection based on 35 U.S.C. §103, except that only the claims in the cited patents or applications are considered prior art. See M.P.E.P. §804. Therefore, the analysis employed in an obviousness-type double patenting rejection parallels the analysis of a 35 U.S.C. §103 obviousness determination, and a *prima facie* case of obviousness must be established. See In re Braat, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991).

Applicant submits that the prior art of record, either alone or in combination, does not teach or suggest every limitation of the pending claims as none of the references teach or disclose a method comprising treating PBMC from a donor with a suppressive composition comprising TGF-β, IL-2 and a T cell activator to ameliorate graft versus host disease. Applicants respectfully request withdrawal of the double patenting rejection.

Claims 29-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-4 of U.S. Patent No. 6, 447, 765 in view of Sykes et al., 1990, Cell Immunol., 129: 478-93.

Sykes et al teach methods for generating natural suppressor cells derived from T cell-deplete bone marrow that express NK1.1, CD3, but not CD4 or CD8. There is no teaching in Sykes for selectively enriching a CD3+CD4-CD8- subset from donor PBMC and then treating that subset with a suppressive composition comprising TGF-β, IL-2 and a T cell activator.

Applicant submits that the prior art of record, either alone or in combination, does not teach or suggest every limitation of the pending claims as none of the references teach or disclose a method comprising treating PBMC from a donor with a suppressive composition comprising TGF-β, IL-2 and a T cell activator to ameliorate graft versus host disease. Applicants respectfully request withdrawal of the double patenting rejection.

Please direct further questions in connection with this Application to the undersigned at (415) 781-1989.

Respectfully submitted,
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By: _____

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